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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/807,949 | 08/09/2001 | Jan Zavada | D-0021.5C-1 | 9458 |

24988 7590 07/02/2007

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|---|---|
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| ART UNIT | PAPER NUMBER |
| 1643 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 07/02/2007 | PAPER |

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**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Application Number: 09/807,949
Filing Date: August 09, 2001
Appellant(s): ZAVADA ET AL.

Leona Lauder
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 2/22/2007 appealing from the Office action mailed 10/13/2006.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

No evidence is relied upon by the examiner in the rejection of the claims under appeal.

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

***Claim Rejections - 35 USC § 112, 1st paragraph***

Claims 31-37,39,41-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case has only set forth a peptide sequence which consists of or comprises the sequence of SEQ ID No: 50 or the sequence of 10 and 98-103, and therefore the written description is not commensurate in scope to the claims that read on a peptide sequence which consists of or comprises a sequence of SEQ ID No: 1, 10, or 98-103 as claimed. The following *written description* rejection is set forth herein.

The claims recite "an amino acid sequence" of any one of SEQ ID No: 50, 10, or 98-10 as part of the invention. This reads on a fragment as small as two amino acid found within the sequence of SEQ ID No: 50, 10, or 98-103. However, there does not appear to be an adequate written description in the specification as-filed that is representative of the fragment as small as two amino acid sequences derived from SEQ ID No: 50, 10, or 98-103, which is encompassed by the claimed peptide sequences. The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by

disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the appellant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 3rd column).

Appellant does not appear to have reduced to practice the broad genus of "an amino acid sequence" derived from either SEQ ID No: 50, 10, or 98-103. Neither has Appellant provided a sufficient written description of any particular structure of "an amino acid sequence " derived from SEQ ID No: 50, 10, or 98-103. "[A]n amino acid sequence" encompasses *any* amino acid sequence, as small as 2 amino acids, found within SEQ ID No: 50, 10, or 98-103. Thus the genus of compounds encompassed by this phrase is extensive and the artisan would not be able to recognize that Appellant was in possession of the invention as now claimed.

Consequently, Appellant was not in possession of the instant claimed invention. See Regents of the University of California v. Eli Lilly and Co. 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). Adequate written description of genetic material "'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention." Id. 43 USPQ2d at 1404 (quoting Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606). The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter of the claim. Id. 43 USPQ2d at 1406. A description of what the genetic

material does, rather than of what it is, does not suffice. Id.

Appellant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001. Appellant is also invited to point to clear support or specific examples of the claimed invention in the specification as-filed.

It is noted that appellant may overcome this rejection by amending the claims to recite a peptide comprising "the amino acid sequence".

***Claim Rejections - 35 USC § 112, 1st paragraph***

Claims 31-37,39,41, and 42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. THIS IS A NEW MATTER REJECTION.

Appellants have amended the claims to include a negative proviso limitation of "the non-MN-portion of said fusion protein or said fusion polypeptide does not contain a cell adhesion site". Appellant directs the examiner to page 21, lines 1-14 and page 69, lines 8-13 for support of this new limitation. However, the pages direct are drawn to the explanation of why the fusion protein would contain an additional binding site to which cells could potentially bind. There is no specific indication or disclosure that support a

negative limitation or specific exclusion of fusion proteins missing a cell adhesion site as now currently claimed.

Appellant is invited to point to clear support or specific examples of the claimed invention in the specification as-filed, by specifically pointing to further support for the negative limitation currently claimed.

It is noted that the art rejections of record do not anticipate the claims as currently presented. However, if appellant reverts to the claims previously presented, wherein there is an exclusion of the negative limitation of no containing a cell adhesion site, the art rejection may be re-applied.

**(10) Response to Argument**

First 35 USC §1 12, ¶1 Rejection is Improper: Use of Formal Markush Group Language

At page 14 of the Brief, Appellant contends that the rejection of the claims under 35 USC § 112, ¶1 is improper because the use of the term "the" is proper and standard Markush group language. In particular, Appellant contends that the use of the term "an" is formal Markush group claim language and would "inherently refer to the full-length amino acid sequence" of the claimed sequences identified by the sequence identification numbers (see Brief page 14). Appellant further contends that the use of the term "the" would lack proper antecedent basis in the claim (see Brief page 14) and that the amendment set forth in paragraph 1 of claim 31 (i.e. using Markush group claim language) overcomes the Written Description issue of a sequence as small as two

amino acids in length. Appellant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

The amendment to the claims do not overcome the written description rejection because the claimed "amino acid sequence" of the site still reads on a sequence as short as two amino acids derived from any of the claimed sequences listed in the Markush group. In other words, limiting the sequence by using Markush type language does not satisfy the lack of written description for a sequence of anything other than the sequence consisting of anyone of SEQ ID No: 10, 98-102, or 103. The use of the term "an" in the claim proceeds the Markush group claim language and because Markush groups are written such that each of the members of the group are in the alternative, the term "an" modifies a single sequence identifier (e.g. 10, 98,99,100,101,102, or 103). Therefore, since a single sequence is being modified and because the claims is written in open/comprising language, the term "an" reads on a sequence as small as two amino acids found within any of the sequence claimed in the Markush group. For the above reasons, it is believed that the rejection should be sustained.

Second 35 USC § 112, ¶1 Rejection is Improper: Rejection of Inherent Characterization as New Matter.

At page 16 of the Brief, Appellant argues that the rejection of the claims for insufficient support in the specification at the time of filing or New Matter is improper. Specifically, Appellant contends that the newly added limitation is a "negative limitation clearly inherent in the Specification." At page 17 of the Brief, Appellant argues that the

addition of the proviso was to make explicit what those of skill in the art would understand from the implicit teachings of the specification.

At page 17 of the Brief, Appellant reviews MPEP § 2163.07(a), a decision from the Board of Patent Appeals and Interferences *Ex parte Soreson*, 4 USPQ2d 1462,1463 (Bd. Pat. App. & Interf. 1987), and MPEP §2173.05(i), all of which the Examiner acknowledged and takes no issue.

At page 18 of the Brief, Appellant points to page 69, lines 8-13 of the specification for the alleged support for the proviso of claim 31. In particular, Appellant argues that the addition of the proviso was based on the concept that the GST-MN fusion protein used was inoperative because the GST portion of the fusion protein contained another binding site which is not blocked by the M75 antibody. Appellant further argues that the instant application is a correction of the inventor's own work (Zavada *et al* (1997) - see Exhibit 2) and to alert those of skill in the art that there an alternative cell binding site in the non-MN portion of the MN-fusion proteins. Appellant further argues, at page 19 of the Brief, that for an effective assay for the detection of molecules that bind to MN's cell adhesion site, the non-MN portion of the fusion protein cannot have a cell binding site. Appellant states that the proviso added simply states an understanding that one of skill in the art would know, which is that the non-MN portion cannot have a cell binding site. Appellant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

Appellants have amended the claims to include a negative limitation such that the non-MN portion of the fusion protein is to lack any cell binding sites in which MN

would be capable of binding. In the office action mailed 2/9/2005, an art rejection over Zavada *et al* (1997) was applied against the claimed invention. This rejection was maintained until the amendment of the claims excluding the cell binding site in the non-MN portion of the fusion protein. The support provided by the appellant does not provide those of skill in the art with any explicit or implicit support that all non-MN portions of the fusion protein should lack or be screened of potential cell binding sites. Even if it were scientifically sound to determine if there are in fact cell binding sites, alternative means could have been used to block those sites such that it would not interfere with the binding assay. The proviso to exclude such a site from the fusion protein is but one means those of skill in the art could have alleviated the problem found in Zavada *et al* (1997). For the above reasons, it is believed that the rejection should be sustained.

**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

Respectfully submitted,

Christopher Yaen
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